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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/276,868

03/26/1999

MICHAEL SIMONS

BIS-043

2716

7590

10/28/2004

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/276,868	<b>Applicant(s)</b> SIMONS ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Status of the Claims*

1. Claims 11-15 are pending.

Applicants' amendment filed August 12, 2004 is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, and claims 11-15 are under examination.

### *Rejection Withdrawn*

#### *Claim Rejections - 35 USC § 112*

2. The previous rejection of claims 11-15, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 9-12 in the amendment filed June 29, 2004.

#### *Claim Rejections-Obviousness Type Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 11-15 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of copending application 10/391,155 (US 2004/0009463). Although the conflicting claims are not identical,

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they are not patentably distinct from each other because claims 11-15 in the instant application disclose a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated or protease-mediated degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, having N-terminal sequence of Arg-Arg-Arg, and being an analog of native PR-39 peptide. This is obvious in view of claims 10-13 of copending application which disclose a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated I $\kappa$ B $\alpha$  degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 39 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and able to interact in-situ with I $\kappa$ B $\alpha$  in the cell. Since the claims of the instant application and those of the copending application are directed to a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated I $\kappa$ B $\alpha$  degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and being an analog of native PR-39 peptide. Thus, claims 11-15 in present application, and claims 10-13 of copending application are obvious variations of a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated I $\kappa$ B $\alpha$  degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acid residues, being at least partially homologous with the N-terminal sequence of native PR-39 peptide, and being an analog of native PR-39 peptide.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate a Terminal Disclaimer has been filed with the response (pages 8-9 of the response), however, the Terminal Disclaimer is not found in the file.

Therefore, the rejection maintains.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blecha *et al.* (WO 96-32129).

Blecha *et al.* teach PR-39 and the truncated analogs such as PR-14, PR-19 and PR-26, some of the peptides can inhibit leukocyte superoxide anion production and attract leukocytes, thus can be used as medicaments that fight infection by attracting leukocytes to a wound site to restrict tissue damage (page 3). The truncated analog PR-14 (RRRPRPPYLPRPRP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:4 (RRRPRPPYLPR, claim 13) or SEQ ID NO: 5 (RRRPRPPY, claim 14), and PR-19 (RRRPRPPYLPRPRPPFFP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:3 (RRRPRPPYLPRRPP, claim 12). These truncated analogs of PR-39 such as PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides, e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-

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39 peptide, would be expected to have the characteristics, traits or properties of the claimed peptides cited in the claim (claims 11 and 15) since they have the same amino acid sequences as the claimed sequence of SEQ ID NO: 3, 4 or 5.

In response, applicants indicate that the rejection made by Examiner is based solely and exclusively upon the legal doctrine of “inherency”, and the basis of “inherency” requires a factual determination of whether those aspects of the claimed subject matter that are not directly taught in the single prior art reference-the missing descriptive information were nonetheless known in the field of the inventions by practitioners ordinarily skilled in that technical area; the Examiner must demonstrate the prior art reference, directly or indirectly, discloses and provides all the requisite elements and particular limitations defined by the claim, as well as identifies the resulting capabilities, properties and traits recited by the claim language with substantial certainty; and Blecha *et al.* teach the synthesized anti-microbial peptides are analogs or truncated peptides of PR-39 peptide such as PR-14, PR-19 and PR-26 peptides, however, only PR-26 analog was found to have anti-microbial activity, the PR-14 and PR-19 analogs failed to show any anti-microbial activity, thus, Blecha *et al.* only teach the limited utility of PR-26 peptide as anti-microbial agent, the reference does not teach to those skill in the art the requisite elements and limitations of applicants’ claimed invention, directly or indirectly (pages 12-42 of the response).

The response has been fully considered, however, the argument is not found persuasive because Blecha *et al.* teach the same truncated PR-39 peptides (e.g., PR-14 and PR-19) as the oligopeptides cited in claims 12, 13 or 14 (e.g., peptides comprising SEQ ID NO:3, 4 or 5), and PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides,

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e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the same properties and traits as the claimed PR-39 oligopeptides. Thus, the properties of the claimed PR-39 oligopeptides such as inhibiting proteasome-mediated degradation, being pharmacologically active, or interacting in-situ with the  $\alpha 7$  subunit of proteasomes in the cytoplasm of the cell would be expected for the peptides of PR-14 and PR-19, even though the cited properties are not indicated in the reference. Please see attached Feit *et al.* (J. Pat. Trade Off. Soc. Vol. 85, No. 1, pages 5-21 (2003)) regarding "inherency".

### ***Conclusion***

4. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

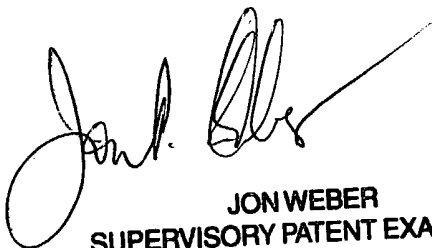
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK  
October 22, 2004

  
JON WEBER  
SUPERVISORY PATENT EXAMINER